

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 24 JUN 2005

10/540764

Applicant's or agent's file reference E1M0056.WO1		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/00543	International filing date (day/month/year) 21.01.2003	Priority date (day/month/year) 21.01.2003	
International Patent Classification (IPC) or both national classification and IPC A61B1/31			
Applicant ANTHEA S.R.L. et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand  06.08.2004		Date of completion of this report  08.04.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840		Authorized Officer  Völlinger, M  Telephone No. +49 30 25901-597	



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International application No. **PCT/EP 03/00543**

**I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

**Description, Pages**

1-8 as originally filed

**Claims, Numbers**

1-26 as originally filed

**Drawings, Sheets**

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item:

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	2-26
	No: Claims	1
Inventive step (IS)	Yes: Claims	
	No: Claims	1-26
Industrial applicability (IA)	Yes: Claims	1-26
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: EP-A-1 234 539 (AMI GMBH) 28 August 2002 (2002-08-28)
- D2: FR-A-2 623 078 (ROUVIERE GILLES) 19 May 1989 (1989-05-19)
- D3: DE 199 29 314 A (ASAHI OPTICAL CO LTD) 30 December 1999 (1999-12-30)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (the references in parentheses applying to this document): A disposable device for surgical operations on the arteria haemorrhoidalis (FIG. 1) comprising

- a retractor tube closed and rounded at the end (tube 1 in FIG. 1), which is provided upon its side surface with at least a window (7 in FIG. 1),
- a gripping handle (2 in FIG. 1; it is not clear what is meant by the term "integral with its external mouth". Therefore, this term has been ignored for construing the claim),
- means to illuminate said window (light guide 10 in FIG. 2) ,
- said illumination means comprises a luminous source (LED 5 in FIG. 1) fixed in removable manner inside said handle (cf. FIG. 4 and paragraph 20: handle 2 including LED can be removed) and comprise at the level of the conjunction zone of the handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (light guide 10 in FIG. 1).

3. Dependent claims 2 - 26 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT), the reasons being as follows:

- 3.1. The use of a mirror as means to reflect light in a speculum is already known from the otoscope disclosed in document D2, cf. page 3, lines 29-32. The choice of a parabolic mirror as a specifically formed mirror comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a speculum according to document D1, thereby arriving at a speculum according to claim 2.
- 3.2. The supplementary features introduced by dependent claims 3 - 21 specify minor implementation details which do not add anything of inventive significance to the subject-matter of claim 1 or 2, respectively, especially as the advantage thus achieved can be readily contemplated in advance.
- 3.3. The additional subject-matter introduced in dependent claim 22 differs from the disclosure of document D1 in that the retractor tube is provided in alignment with the exploration window and, upstream of this, with a small longitudinal, rectilinear and internal chamber delimited by a baffle which is integral with the internal walls of the tube and with the posterior side of the window, the whole in such a manner that the chamber results opened toward the mouth of the tube, there being provided that in said chamber is friction-housed an ultrasonic probe which is partially projecting through an opening longitudinally obtained on the lateral wall of the retractor tube, in such a manner that the same probe results to be in contact with the anal mucosa.

The problem to be solved by these additional features may therefore be regarded as to provide an improved disposable device for surgical operations on the arteria haemorrhoidalis with the ultrasonic probe not being integral with the retractor tube thereby permitting the use of a reusable ultrasonic probe in the disposable retractor tube.

In this connection, document D3 discloses an endoscope for ultrasonic examination and surgical treatment comprising an elongated insertion portion and a probe insertion channel extending along the insertion portion, the probe insertion portion having an opening at the distal end of the elongated insertion portion opened in

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direction substantially lateral with respect to the elongated insertion portion (see claims 1 and 6; Fig. 3,5).

As a consequence, document D3 would point the skilled person dealing with the posed problem, to include a probe insertion channel for housing an ultrasonic probe in the device of document D1 thereby arriving at the subject-matter of claim 22 without involving an inventive step (Article 56 EPC).

- 3.4. The supplementary features introduced by dependent claims 23 - 26 specify minor implementation details which do not add anything of inventive significance to the subject-matter of claim 22 especially as the advantage thus achieved can be readily contemplated in advance.